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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,319	03/31/2000	Robert Justice Shartle	LFS-93	1316
7590	02/04/2004		EXAMINER	
PHILIP S JOHNSON One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003			NASSER, ROBERT L	
			ART UNIT	PAPER NUMBER
			3736	
			DATE MAILED: 02/04/2004	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/540,319	SHARTLE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on rce filing of 10/20/2003.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8 and 11-13 is/are rejected.

7) Claim(s) 9 and 10 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> .	6) <input type="checkbox"/> Other: _____

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-8, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al 6,258,229 in view of Charlton et al 5,798,031 and Hodges WO 97/18464. Winarta et al shows a biosensor having a first layer 20 with a metallized layer 21 having two insulating patterns scored therein to divide the layer into 3 separated conductive portions, an insulating middle layer having a cutout 32, and an insulating top layer, cover 40. The cover is not conductive. However, Charlton et al further teaches that non-conductive and conductive covers are equivalents for the purposes of Winarta (see column 3,lines 50-62). Hence, it would have been obvious to modify Winarta to use a conductive cover, as it is merely the substitution of one known equivalent cover for another. The cover of the combination is not an insulative layer with a conductive layer, but rather an aluminum foil layer. However, Hodges teaches it is known to use metallized thermoplastic layers in biosensor like Winarta. Hence, it would have been obvious to modify the combination to use an insulator with a conductive layer, as it is merely the substitution of one known equivalent conductive layer for another. In addition, Winarta has a reagent having an enzyme, a buffer, and a mediator. When the sample flows through the cutout, it reaches the cell before the first insulating pattern and hits the 2<sup>nd</sup> pattern before flowing through the cell. With respect to claim 7, Charlton teaches having the insulating layer be a thermoplastic material.

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Hence, it would have been obvious to modify Winarta to use such a material, as it is merely the substitution of one insulator for another. The combination has the remaining claim features.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al in view of Charlton et al and Hodges, as applied to claims 1, 2, 4-8, 11, and 12 above, and further in view of Pritchard WO 97/02487. The combination has both the scoring and the reagent on the same side of the middle layer. Pritchard shows an alternative arrangement where they are on opposite sides of the insulating middle layer. Hence, it would have been obvious to modify the above combination to use the configuration of Pritchard, as it is merely the substitution of one known equivalent arrangement for another.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al in view of Charlton et al and Hodges, as applied to claims 1, 2, 4-8, 11, and 12 above, and further in view of Feldman et al 6,461,496. Feldman et al further teaches that it is desirable to use a fill detecting circuit to prevent partial filling of the chamber and produce erroneous measurements (see column 51, lines 2-30). Hence, it would have been obvious to include such a fill detection circuit, to prevent false readings.

Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 9 and 10 define over the art of record in that none of the art shows the serration, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*RLN & Nasser*

Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
January 25, 2004

ROBERT L. NASSER  
PRIMARY EXAMINER